



Heritage Information Systems, Inc.



## Clinical Edit Criteria Proposal

Drug/Drug Class: **Antibiotic RTU Pack Clinical Edit**

Prepared for: **Missouri Medicaid**  
Prepared by: **Heritage Information Systems, Inc.**

☒ **New Criteria**

☐ **Revision of Existing Criteria**

### Executive Summary

**Purpose:** Limit the number of prescription refills for ready-to-use antibiotic packs to one pack per month.

**Why was this Issue Selected:** Several antimicrobial products are manufactured in ready-to-use (RTU) packaging that simplifies prescribing and dispensing for physician and pharmacist providers. The simplicity associated with the prescribing of these products also creates a potential for over utilization, especially when initial therapy fails and a refill of the same product is requested. Refills of these products increase the opportunity for bacterial resistance. Antimicrobial products currently packaged as RTU include: azithromycin (Z-Pak), ciprofloxacin (Cipro Cystitis Pack), clarithromycin (Biaxin XL), dirithromycin (D-5 PAC), gatifloxacin (TEQ-PAC), and moxifloxacin (ABC PAC).

	Drug	Claims	Expense
<b>Program-specific information:</b> <b>(Mar 2002 – Feb 2003)</b>	• Zithromycin 250mg Tablets	127,057	\$4,561,217
	• Ciprofloxacin 100mg Tablets	47,878	\$3,398,505
	• Clarithromycin 500mg XL Tablets	12,571	\$876,096
	• Dirithromycin 250mg Tablets	1,573	\$84,152
	• Gatifloxacin 400mg Tablets	8,720	\$599,392
	• Moxifloxacin 400mg Tablets	9,091	\$675,098

**Setting & Population:** Prescribed in patients 16 years of age and older with infection.

**Type of Criteria:** ☐ **Increased risk of ADE** ☐ **Non-Preferred Agent**  
☒ **Effectiveness** ☐ **Other**

**Data Sources:** ☒ **Only administrative databases** ☐ **Databases + Prescriber-supplied**

## Setting & Population

- Drug/drug class for review:
  - azithromycin (Z-Pak and TRI-PAKS),
  - ciprofloxacin (Cipro Cystitis Pack®)
  - clarithromycin (Biaxin XL PAC®),
  - dirithromycin (D-5 PAC),
  - gatifloxacin (TEQ-PAC), and
  - moxifloxacin (Avelox ABC Pack®).
  - Ciprofloxacin (Cipro XR 500®)
- Age range:  $\geq 16$  years of age
- Gender: males and females

## Approval Criteria

- Therapy is approved if none of the denial criteria are met

## Denial Criteria

- Refill within 30 days of initial prescription claim.
- Denial requests may be overridden based on the override diagnosis included in the table below for each respective agent.

Generic Name	Brand Name	Dose	No. of Tablets	Days of therapy	Override Diagnosis <sup>1</sup>
Azithromycin	Z-pak® TRI-PAKS™	250mg 500mg	#6 #3	5 3	• None
Ciprofloxacin	Cipro Cystitis Pack®	100mg	#6	3	• None
Clarithromycin XL	Biaxin XL PAC®	500mg	#14	7	• Acute maxillary sinusitis
Dirithromycin	Dynabac D5 Pak™	250mg	#10	5	• CAP* • Pharyngitis/Tonsillitis
Gatifloxacin	TEQ-PAC ®	200mg 400mg	#7	7	• CAP*
Moxifloxacin	Avelox ABC Pack®	400mg	#5	5	• Acute bacterial sinusitis • CAP*
Ciprofloxacin	Cipro XR ®	500mg	#3	3	• Acute UTI

\*CAP = community acquired pneumonia



## Required Documentation

Culture and Sens: ☒  
MedWatch form: ☐

Progress notes: ☐  
☐

## Disposition of Edit

- **Denial:** Edit 682 "Clinical Edit"

## References

1. Lippincott, Williams, Wilkins. PDR Electronic Library, Montvale NJ; 2003.

## Client Approval

Please have an authorized representative execute this Clinical Edit criteria verifying receipt by the client and that all elements contained herein are understood.

Client Name: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

